UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

SAM DESABIO,

Plaintiff,

v.

DECISION AND ORDER
09-CV-287S

HOWMEDICA OSTEONICS CORP. and
STRYKER CORPORATION,

Defendants.

I. INTRODUCTION

Plaintiff Desabio commenced this action in New York State Supreme Court, County of Erie, on or about February 20, 2009, alleging claims for breach of express warranty, carelessness and negligence, and breach of implied warranty relating to an allegedly defective hip prosthesis he received. Defendants, the alleged manufacturers and sellers of the prosthesis, removed the action to this Court, and subsequently moved for partial dismissal and for a more definite statement. In response, Plaintiff amended his Complaint, asserting claims for negligent design and/or manufacture, breach of warranty, and res ipsa loquitur. (Docket No. 12.)

Now before the Court are Defendants' Motion to Dismiss the Amended Complaint in its entirety (Docket No. 10), and Plaintiff's Motion to Amend/Correct Amended Complaint (Docket No. 14). Plaintiff seeks to revise his negligence claim to allege a failure to comply with Food and Drug Administration ("FDA") standards in the manufacturing process. The

motions are fully briefed,[1] and the Court finds that no oral argument is necessary. For the reasons discussed below, Plaintiff's motion is denied, and Defendants' motion is granted.

II. DISCUSSION

This case involves an artificial hip prosthesis, known as the Trident™ System,[2] which has been classified by the FDA as a Class III medical device. According to Plaintiff, after the Trident System was implanted, in or about April 12, 2005, the device squeaked and he "suffered severe grinding and pain." (Docket No. 12 ¶¶ 9, 12.) In his Amended Complaint, Plaintiff asserts claims for negligent design and/or manufacture, breach of warranty, and res ipsa loquitur.

Defendants urge that these common law claims must be dismissed because they are preempted by the Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. § 360k, to the Federal Food, Drug and Cosmetics Act ("FDCA"), and also because Plaintiff has failed to adequately plead them.

In response, Plaintiff contends that his negligence and res ipsa loquitur claims implicitly assert violations of FDA standards, and that his breach of warranty claim survives as a "parallel claim." Alternatively, Plaintiff seeks leave to amend his negligence claim to specifically reference the FDA and thereby purportedly cure any pleading defect.

Defendants argue that Plaintiff has not presented any "parallel claim" and that his

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[1] Defendants included their opposition to Plaintiff's motion in their Reply in further support of their motion to dismiss.

[2] Plaintiff refers to the device, upon information and belief, as a "Styrker [sic] Ceramic Hip Replacement." (Docket No. 12 ¶ 10.) Defendants state the device is a "Trident™ Ceramic on Ceramic Acetabular System." (Docket No. 10-2 at 7.) For purposes of this motion, the at-issue hip prosthesis will be referred to as "the Trident System."

proposed second amended pleading is insufficient to salvage his negligence claim.

A. Applicable Standards of Review

1. *Motion to Dismiss*

Federal pleading standards are generally not stringent. Rule 8 requires only a short and plain statement of a claim. FED. R. CIV. P. 8(a)(2). But the plain statement must "possess enough heft to show that the pleader is entitled to relief." Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 557, 127 S. Ct. 1955, 167 L. Ed. 2d 929 (2007) (internal quotation marks omitted).

When determining whether a complaint states a claim, the court must construe it liberally, accept all factual allegations as true, and draw all reasonable inferences in the plaintiff's favor. ATSI Commc'ns, Inc. v. Shaar Fund, Ltd., 493 F.3d 87, 98 (2d Cir. 2007); Goldstein v. Pataki, 516 F.3d 50, 56 (2d Cir. 2008). Legal conclusions, however, are not afforded the same presumption of truthfulness. *See* Ashcroft v. Iqbal, __ U.S. __, 129 S.Ct. 1937, 1949, 173 L. Ed. 2d 868 (2009) ("the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions").

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Iqbal, 129 S.Ct. at 1945 (quoting Twombly, 550 U.S. at 570). Labels, conclusions, or "a formulaic recitation of the elements of a cause of action will not do." Twombly, 550 U.S. at 555. Facial plausibility is present when the factual content of the complaint allows for a reasonable inference that the defendant is liable for the misconduct alleged. Iqbal, 129 S.Ct. at 1949. The plausibility standard is not, however, a probability requirement; the pleading must

show, not merely allege, that the pleader is entitled to relief. *Id.* at 1950; FED. R. CIV. P. 8(a)(2). Well-pleaded allegations in the complaint must nudge the claim "across the line from conceivable to plausible." Twombly, 550 U.S. at 570.

A two-pronged approach is thus used to examine the sufficiency of a complaint. First, statements that are not entitled to the assumption of truth — such as conclusory allegations, labels, and legal conclusions — are identified and stripped away. *See* Iqbal, 129 S.Ct. at 1950. Second, well-pleaded, non-conclusory factual allegations are presumed true and examined to determine whether they "plausibly give rise to an entitlement to relief." *Id.*

2. *Motion to Amend*

Pursuant to Rule 15(a) of the Federal Rules of Civil Procedure, leave to amend a pleading shall be freely given when justice so requires. *See* Livingston v. Piskor, 215 F.R.D. 84, 85 (W.D.N.Y. 2003). "Absent evidence of undue delay, bad faith or dilatory motive on the part of the movant, undue prejudice to the opposing party, or futility, Rule 15's mandate must be obeyed." Monahan v. New York City Department of Corrections, 214 F.3d 275, 283 (2d Cir. 2000) (citing Foman v. Davis, 371 U.S. 178, 182, 83 S. Ct. 227, 9 L. Ed. 2d 222 (1962)), *cert. denied*, 531 U.S. 1035 (2000).

B. The FDA's Premarket Approval (PMA) of the Trident System

The FDA's regulatory regime under the MDA establishes three levels of oversight for medical devices, depending on the risks they present. Riegel v. Medtronic, Inc., 552 U.S. 312, 316, 128 S. Ct. 999, 169 L. Ed. 2d 892 (2008). Devices receiving the most federal oversight are those in Class III. *Id*. at 317. The Trident System is classified as a

Class III device, which includes devices "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health," or "presents a potential unreasonable risk of illness or injury," and for which it cannot be established that a less stringent (Class I or Class II) classification would provide reasonable assurance of safety and effectiveness. 21 U.S.C. § 360c(a)(1)(C).

A new Class III device must undergo a premarket approval process ("PMA"), unless the FDA finds it is "substantially equivalent" to a device that already was on the market prior to the MDA's effective date and was "grandfathered" in under the statute. *Id*. § 360c(f)(1). Most new devices enter the market through this "substantially equivalent" process, also known as the § 501k process. For example, in 2005, the FDA authorized the marketing of 3,148 devices under § 510(k), while just 32 devices were granted premarket approval. Riegel, 552 U.S. at 317. The PMA process is a "rigorous" one, and this is the process the FDA required for the Trident System.[3] Gelber v. Stryker Corp., 752 F. Supp. 2d 328, 331 (S.D.N.Y. 2010).

As more fully discussed in Riegel, the PMA process involves the submission of voluminous, comprehensive information on the device—including, among other things, full reports of all studies and investigations, a full description of the methods used in, and the

[3] When Defendants filed their motion, in 2009, they cited web addresses for, *inter alia*, the FDA's approval letter relative to the PMA application for the Trident System. Those addresses, assuming they were once correct, no longer lead to information on the Trident System.

The Court was able to confirm, through a search of the FDA's website conducted on September 7, 2011, that the Trident System was assigned PMA Number P000013, and the application was approved on February 3, 2003. *See* http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm?id=19609. The Court takes judicial notice of this fact.

facilities and controls used for, the manufacture and processing of the device, samples of the device components, and a specimen of the proposed labeling—and the FDA spends an average of 1,200 hours reviewing each application. 552 U.S. at 18-19 (citing Medtronic, Inc. v. Lohr, 518 U.S. 470, 477, 116 S. Ct. 2240, 135 L. Ed. 2d 700 (1996)). The FDA may choose to refer an application to a panel of outside experts, 21 C.F.R. § 814.44(a), and may request that the manufacturer provide additional data, 21 U.S.C. § 360e(c)(1)(G). Premarket approval is granted only if the FDA finds there is a reasonable assurance of the device's safety and effectiveness. 21 U.S.C. § 360e(d).

Upon completion of the PMA process for the Trident System, the FDA approved the device as safe and effective for its intended use. *Supra*, fn. 3. After approving a Class III device, the FDA retains regulatory control and the manufacturer is prohibited from changing design specifications, manufacturing processes, labeling, or any other attribute that would affect its safety or effectiveness. Riegel, 552 U.S. at 319 (citing 21 U.S.C. § 360e(d)(6)(A)(i)).

C. MDA Preemption

The MDA contains a preemption clause, which states that:

> Except as provided in subsection (b)[4] of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

[4] The exception contained in subsection (b) permits the FDA to exempt some state and local requirements from preemption. 21 U.S.C. § 360k(b). There is no allegation that any such exemption has been granted in New York state with regard to the Trident System.

21 U.S.C. § 360k(a).

In Riegel, the Supreme Court interpreted this clause as preempting state law claims when (a) the federal government has established specific requirements applicable to the device, and (b) the state law claims are based on requirements that are "different from, or in addition to the federal ones" and relate to the safety and effectiveness of the device. 552 U.S. at 321-22; *see also* 21 U.S.C. § 360k(a)(1). The Court found that, because a PMA is specific to the particular device in question and is entirely concerned with the safety and effectiveness of the device, it imposes "specific requirements" and thus meets the first preemption requirement. Riegel, 552 U.S. at 322-23. The Court further concluded that common law claims involving a medical device are premised on the existence of a legal duty, and therefore impose state "requirements" that would be preempted by device-specific federal requirements. *Id*. at 323-324 (citing Lohr, 518 U.S. at 512). The majority specifically noted that, although the dissenting member had difficulty believing that Congress would remove all means of judicial recourse for consumers injured by Class III PMA devices, "this is exactly what a preemption clause for medical devices does by its terms." *Id*. at 326.

Riegel went on to explain that not all state-law claims relating to approved devices are foreclosed. "[Section] 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." 552 U.S. at 330 (citing Lohr, 518 U.S. at 495). But the Court declined to provide further guidance on this issue because the plaintiffs had not raised their "parallel claims" argument below or in their petition for certiorari. That has left post-Riegel courts with the task of determining the circumstances

in which state law claims remain available as "parallel" to federal requirements. Plaintiff's claims, in both his Amended Complaint and proposed second amended complaint, are considered in light of Riegel and subsequent relevant decisions.

D. Analysis

1. *Plaintiff's Negligence Claim*

a. The Amended Complaint's First and Third Causes of Action

Plaintiff claims in his Amended Complaint that the Trident components he received were "improperly, carelessly and negligently manufactured and/or inadequately improperly and carelessly designed." (Docket No. 12 ¶ 11.) He goes on to assert that, even absent evidence of negligence, "the component parts were developed and manufactured by the Defendants and/or others who were solely in the control of the Defendants" such that negligence is presumed under the doctrine of res ipsa loquitur. (*Id.* ¶¶ 20-21.) In short, Plaintiff's first and third claims for relief are based squarely on Defendants' purported breach of state tort duties of care. Common law negligence claims are precisely the type of claims Riegel held are preempted by the MDA. 552 U.S. 320-21, 330 (affirming holding that strict liability, negligence, and breach of implied warranty claims under New York's common law were expressly preempted).

Indeed, since Riegel, a number of courts have dismissed negligence and other tort claims in actions involving the Trident System based on the MDA's preemption clause. *See, e.g.,* Funk v. Stryker, 673 F. Supp.2d 522 (S.D. Tex. 2009), *aff'd*, 631 F.3d 777 (5th Cir. 2011) (finding claims for strict liability, negligence, and breach of implied warranty preempted, and rejecting doctrine of res ipsa loquitur on ground that PMA process

amounts to federal declaration that product, while not risk-free, is not unreasonably dangerous in light of potential benefits, and it follows that negligence cannot be inferred solely from negative side effect); Lemelle v. Stryker Orthopaedics, 698 F. Supp. 2d 668 (W.D. La. 2010) (breach of implied warranty preempted); Anthony v. Stryker Corp., No. 09-CV-2343, 2010 U.S. Dist. LEXIS 31031 (N.D. Ohio Mar. 31, 2010) (dismissing with prejudice claims for strict liability, negligence, breach of implied warranty, breach of express warranty, and misrepresentation); Delaney v. Stryker Orthopaedics, No. 08-03210, 2009 U.S. Dist. LEXIS 16865 (D. N.J. Mar. 5, 2009) (dismissing claims for failure to warn, strict liability, negligence and recklessness, and breach of implied warranties as preempted by MDA); Horowitz v. Stryker Corp., 613 F. Supp. 2d 271 (E.D.N.Y. 2009) (dismissing claims for strict liability, negligence and recklessness, and breach of express and implied warranties).

In opposition to Defendants' motion, Plaintiff argues that his first and third claims adequately plead a violation of FDA regulations, and therefore are parallel claims that cannot be preempted. But the only fact allegations on which Plaintiff's negligence claim rests is that, after implantation, the Trident System squeaked with severity and Plaintiff suffered severe grinding and pain. These allegations simply do not implicate a violation of federal law. Accordingly, as pleaded in Plaintiff's Amended Complaint, his first and third claims are preempted and must be dismissed.

b. The Proposed Second Amended Complaint

Plaintiff next argues that, in the event the Court finds his negligence claim preempted—as it has—he should be granted leave to file the proposed second amended complaint that he submitted in response to Defendants' motion to dismiss. As previously

noted, Rule 15(a) of the Federal Rules of Civil Procedure provides that leave to amend should be freely given when justice so requires. In this instance, however, leave to amend is denied.

Plaintiffs' proposed second amended complaint is identical to the Amended Complaint but for the addition of four paragraphs to the first cause of action, only three of which refer to federal law. They state, in pertinent part, that:

> The Defendants were negligent in that the aforesaid components were unreasonably dangerous and defective as the manufacturing process for said components were not in compliance with the [FDA's] [PMA] standards for Class III devices in general and this device in particular
>
> [T]he implanted components were defectively manufactured and not in compliance with the requirements approved by the FDA and had an impurity, imperfection and/or other product defects allowed to be created, contained or placed within the product in the Defendant's manufacturing process
>
> [T]his impurity, imperfection and or other product defects were a deviation from the Defendants' design and quality manufacturing standards for the [Trident System] approved by the FDA

(Docket No. 14-2 ¶¶ 11-13.) These new allegations of a manufacturing defect resulting from Defendants' violation of unspecified "general" and "particular" federal standards are supported by precisely the same facts as appear in the Amended Complaint—*i.e.*, that Plaintiff experienced squeaking, grinding, and pain after receiving a Trident System implant. Plaintiff urges that he should be permitted to conduct discovery so he can determine "how the plaintiff [sic] violated FDA standards" and "where exactly the negligence occurred." (Docket No. 15-3 at 7.)

The new allegations appear to be drawn directly from Hofts v. Howmedica Osteonics Corp., the sole case on which Plaintiff relies in opposition to Defendants' motion and in support of the viability of his proposed second amended complaint. 597 F. Supp. 2d 830

(S.D. Ind. 2009). In Hofts, the district court allowed the plaintiff's claims for defective manufacture to proceed as a "parallel claim" on substantially similar and conclusory allegations, reasoning that to hold otherwise would amount to "an unusually stringent application of Twombly and Rule 8 of the Federal Rules of Civil Procedure at the motion to dismiss stage." 597 F. Supp. 2d at 838. This Court respectfully disagrees.

In Twombly, the Supreme Court explained that "something beyond the mere possibility of [a federal violation] must be alleged, lest a plaintiff with a largely groundless claim be allowed to take up the time of a number of other people, with the right to do so representing an *in terrorem* increment of the settlement value." 550 U.S. at 557-58 (citing Dura Pharms., Inc. v. Broudo, 544 U.S. 336, 347, 125 S. Ct. 1627, 161 L. Ed. 2d 577) (2005). Thus, "a district court must retain the power to insist upon some specificity in pleading before allowing a potentially massive factual controversy to proceed [to discovery]." *Id*. The operative word in the prior sentence is "some." Neither Rule 8 nor Twombly require that a plaintiff plead facts in support of each element of a claim. Nevertheless, the complaint must have enough factual content to allow for a reasonable inference that the defendant is liable for the misconduct alleged. Iqbal, 129 S.Ct. at 1949. Plaintiff's allegation that the Trident System did not resolve his pain and mobility problems in the manner he anticipated, without more, does not reasonably allow for the inference that Defendants violated federal law.

"In line with the majority of courts who have addressed pleading standards in this context, the Court agrees that 'Plaintiffs cannot simply incant the magic words [Stryker] violated FDA regulations in order to avoid preemption.'" Gelber, 752 F. Supp. 2d at 334 (quoting In re Medtronic, 592 F. Supp. 2d 1147, 1158 (D. Minn. 2009)) (alteration in

Gelber). "'To properly allege parallel claims, the complaint must set forth facts' pointing to specific PMA requirements that have been violated." Wolicki-Gables v. Arrow Int'l, Inc., 634 F.3d 1296, 1301 (11th Cir. 2011) (quoting Parker v. Stryker Corp., 584 F. Supp. 2d 1298, 1301 (D.Colo. 2008))). Plaintiffs must also allege a link between the failure to comply and the alleged injury. Wolicki-Gables, 634 F.3d at 1301-02 (citing Ilarraza v. Medtronic. Inc., 677 F. Supp. 2d 582, 589 (E.D.N.Y. 2009)).

Plaintiff's vague, proposed amendments are readily distinguished from pleadings that have been found to state parallel claims. For example, in Purcel v. Advanced Bionics, the court determined plaintiff successfully stated a parallel claim where he alleged that a particular malfunction causing his injury was due to a supplier's unapproved modification of a component part of the regulated device. No. 07-CV-1777, 2008 U.S. Dist. LEXIS 62131, at *3 (N.D. Tex. Aug. 13, 2008). Unlike the pleading here, the pleading with respect to the modification in Purcel identified a particular federal specification referring to the device at issue that the defendant allegedly violated. Similarly, in Rollins v. St. Jude Medical, the plaintiff was found to have stated a parallel claim where he was able to point to an alleged violation of premarketing packing requirements applicable to the particular medical device at issue. 583 F. Supp.2d 790, 800-01 (W.D. La. 2008). And, in Bausch v. Stryker Corp., the Seventh Circuit reversed the district court's dismissal of the plaintiff's parallel claim where her original complaint alleged that, prior to her surgery, defendants had received complaints their product was failing, they had recalled some components for "dimensional anomalies," and the FDA had informed defendants of "numerous deficiencies" in the manufacturing and inspection processes and had later issued a warning letter to them. 630 F.3d 546, 559 (7th Cir. 2010). The Court acknowledged that the

complaint would have been stronger had the plaintiff specified the precise product defect or the specific federal requirements violated, but found she had pled with enough specificity to satisfy Rule 8 and Twombly. *Id*. at 559-60.

Here, in an effort to avoid dismissal, Plaintiff seeks to amend what was a straightforward common law negligence claim to plead a claim premised on the violation of federal law. Because his factually unsupported legal conclusions are insufficient to satisfy the notice pleading and plausibility standards for stating a parallel claim, Plaintiff's motion for leave to file his proposed second amended complaint is futile, and is denied.

2. *The Second Cause of Action—Breach of Express Warranty*

The claims for breach of express warranty, as set forth in the Amended complaint and proposed second amended complaint, are identical. Plaintiff alleges his physicians advised him that Defendants warranted the Trident System as being "of good and merchantable quality and fit for the purposed [sic] for which they were intended, to wit: replace a defective hip in Plaintiff's body." (Docket No. 12 ¶¶ 14-15.) He claims that Defendants breached that warranty because the Trident System he received was not of merchantable quality nor fit for its intended purpose. (*Id*. ¶ 19.)

Defendants contend that this claim,[5] too, is preempted by the MDA. Plaintiff, again relying on Hofts, contends that it must survive as a parallel claim.

Riegel did not address an express warranty claim. Nevertheless, numerous cases since have applied Riegel's analysis and concluded that claims for breach of express

[5] Defendants argue that this is so regardless of whether Plaintiff is alleging a claim for breach of implied warranty or breach of express warranty. Plaintiff makes clear in his opposing memorandum that he is claiming breach of express warranty only.

warranty are preempted by the MDA. Quite recently, the District Court for the Northern District of Georgia reasoned that, in order to prove breach of an express warranty, a plaintiff would need to show that the device was not fit for its intended use, and such a finding "would directly conflict with the FDA's premarket approval of the device as reasonably safe and effective," such that preemption applies. Leonard v. Medtronic, Inc., No. 10-CV-03787, 2011 U.S. Dist. LEXIS 93176, at *30 (N.D. Ga. Aug. 19, 2011). As in the instant case, the plaintiffs in Leonard argued that they were not challenging the FDA-approved product labeling as defective, but rather, were alleging that the device did not live up to the FDA-approved promises in the label.[6] *Id*. at *31. The district court concluded, and this Court agrees, that a finding that a defendant violated state law by not living up to FDA-approved promises would necessarily conflict with the FDA's determination that the label was not false or misleading. *Id*. at *32. In other words, it would impose additional and different requirements that would necessarily disrupt the federal scheme, and preemption applies. *See also*, In re Medtronic, Inc., 592 F. Supp. 2d at 1164 (to find in favor of a plaintiff on express warranty claims, a jury would be required to conclude the device was unsafe, and safety and effectiveness of device is matter solely for the FDA); Wheeler v. DePuy Spine, Inc., 706 F. Supp. 2d 1264, 1271 (S.D. Fla. 2010) (allowing claim that defendant breached warranty in FDA-approved document to proceed under state law would impose a requirement on device that was different from or in addition to federal requirements); Horowitz, 613 F. Supp. 2d at 285 (citing Parker, 584 F. Supp. 2d at 1303 (express warranty claim would contradict FDA's determination that label was adequate and

[6] Plaintiff makes precisely this argument in his opposing memorandum. (Docket No. 15-3 at 8.)

appropriate)).

Based on the foregoing, this Court finds Plaintiff's reliance on Hofts is misplaced. Because his express warranty claim would disrupt the federal scheme by imposing additional or different requirements on Defendants, the second cause of action is preempted.

III. CONCLUSION

For the reasons stated, Plaintiff's motion for leave to file his proposed amended complaint is denied as futile, and Defendants' motion to dismiss the Amended Complaint is granted in its entirety.

IV. ORDERS

IT HEREBY IS ORDERED that Plaintiff's Motion to Amend/Correct Amended Complaint (Docket No. 14) is DENIED.

FURTHER that Defendants' Motion to Dismiss Amended Complaint (Docket No. 10) is GRANTED.

FURTHER that the Clerk of Court is directed to close this case.

SO ORDERED.

Dated: September 11, 2011
Buffalo, New York

/s/William M. Skretny
WILLIAM M. SKRETNY
Chief Judge
United States District Court